## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named

Inventor: Neil David Hammond Raven Examiner: Deborah K. Ware

Serial No.: 10/614.370

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Filing Date: July 8, 2003 Group Art Unit No. 1651

Title: DEGRADATION AND DETECTION
OF TSE INFECTIVITY

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir.

In accordance with the provisions of 37 C.F.R. § 1.56, Applicants request that citation and examination of the references identified on the attached Form PTO-1449, required copies of which are enclosed herewith in accordance with 37 C.F.R. § 1.36, be made during the course of examination of the above-referenced application for United States Letters Patent.

Since this Information Disclosure Statement is being submitted after the mailing of the first Office Action, payment of the fee set forth in 37C.F.R. §1.17(p) accompanies this submission

- Payment by credit card. Form PTO-2038 is attached.

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Form PTO-1449 (Rev. 8-88)	Attorney Docket No. MSQ01-002-CIP-US	Serial No. 10/614,370
	First Named Inventor Neil David Hammond Raven	
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date: July 8, 2003	Group: 1651

U.S. PATENT DOCUMENTS							
Examiner Initiats*		Document Number	Date	Name	Class	Subclass	Filling Date If Appropriate
	Z1	RE 34,606	05/1994	Estell, et al.			
	Z2	4,994,200	02/1991	Disch, et al.			
	Z3	5,182,204	01/1993	Estell, et al.			
	Z4	5,185,258	02/1993	Caldwell, et al.			
	Z5	5,204,015	04/1993	Caldwell, et al.			
	Z6	5,700,676	12/1997	Bott, et al.			
	Z7	5,783,257	06/1998	Bott, et al.			
	Z8	5,801,038	09/1998	Bott, et al.			
	Z9	6,312,936	11/2001	Poulose, et al.		<b></b>	
	Z10	6,613,505	09/2003	Shih			

## FOREIGN PATENT DOCUMENTS Examiner Initials\* Translation Document Number Date Country Class Subclass Yes No 0 251 446 01/1988 EP Y2 0 328 299 08/1989 EP Y3 0 723 590 12/2004 EP **Y4** 1 526 182 04/2005 EP Y5 WO 00/29849 05/2000 WO Y6 WO 00/22438 04/2000 WO Y7 WO 89/06279 07/1989 WO Y8 WO 95/10615 04/1995 WO

Examiner		OTHER ITEMS - NON PATENT LITERATURE DOCUMENTS
Initiats*		Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Perlinent Pages
	X1	Bajorath, J., et al., "The enzymatic activity of proteinase K is controlled by calcium"., European Journal of
		Biochemistry, vol. 176, pp. 441-447, (1988).

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X2	Bauer, C., et al., "Purification of a PrP-Dimer expressed in E. coli", Infection, P-201, vol. 28, supplement no. 1, pp. 51, (2000).
Х3	Bernouli, C., et al., "Danger of accidental person-to-person transmission of creutzfeldt-jakob disease by surgery"., The Lancet, pp. 478-479, (1977).
X4	Bolton, D.C., et al., "Identification of a protein that purifies with the scrapie prion"., Science, vol. 218, pp. 1309- 1311, (1982).
Х5	Caughey, B., et al., "Scrapie infectivity correlates with converting activity, pretease resistance, and aggregation of scrapie-associated prion protein in guanidine denaturation studies", Journal of Virology, vol. 71, no. 5, pp. 4107-4110, (1997).
X6	Cho, H.J., "Requirement of a protein component for scrapie infectivity", Intervirology, vol. 14, pp. 213-216, (1980).
X7	Cho, H.J., "Inactivation of the scrapie agent by pronase"., Can. J. Comp. Med., vol. 47, pp. 494-498, (1983).
X9	Ebeling, W., et al., "Proteinase K from Tritirachium album limber"., European Journal of Biochemistry, vol. 47, pp. 91-97, (1974).
X10	Haki, G.D., et el., "Developments in industrially important thermostable enzymes: e review"., Bioresource Technology, vol. 89, pp. 17-34, (2003).
X12	Herbert, R.A., "A perspective on the biotechnological potential of extremophiles", Trends in Biotechnology, vol. 10, pp. 395-402, (1992).
X13	Hunter, G.D., "The enigma of the scraple agent. Biochemical approaches end the involvement of membranes and nucleic edds", Slow transmissible diseases of the nervous system, eds. Prusiner & Hadlow, Academic Press, Inc., vol. 2, pp. 395-385, (1979).
X14	Hunter, G.D., et al., "Attempts to release the screpie agent from tissue debris"., J. Comp. Path., vol. 77, pp. 301-307, (1967).
X15	Hunter, G.D., et al., "Further studies of the infectivity end stability of extracts and homogenates derived from scrapie affected mouse brains", J. Comp. Path., vol. 79, pp. 101-108, (1969).
X16	Kocisko, D.A., et el., "Cell-free formation of protease-resistant prion protein", Nature, vol. 370, pp. 471-474, (1994).
X17	Kristjansson, J.K., "Thermophilic organisms as sources of thermostable enzymes"., Trends in Biotechnology, vol. 7, pp. 349-353, (1989).
X18	Laurenson, I.F., et al., "Contaminated surgical instruments and variant Creutzfeldt-Jakob disease"., The Lancet, vol. 354, pp. 1823, (1999).
X19	Meyer, R.K., et al., "A monomer-dimer equilibrium of a cellular prion protein (PrP) not observed with recombinant PrP", The Journal of Biological Chemistry, vol. 275, no. 48, issue of December 1, pp. 38081- 33087, (200
X20	Milson, G.C., et al., "The physico-chemical nature of the scrapie agent", Slow virus diseases of animals and man, Chapter 11, edited by R.H. Kimberlin, North-Holland Publishing Company, pp. 243-266, (1976).
X21	NG, T.K., et al., "Industrial applications of thermostable enzymes"., Thermophiles: General, Molecular and Applied Microbiology, Brock TD Editor, John Wiley and Sons, chapter 9, pp. 197-215, (1986).
X22	Priola, S.A., et al., "A 60-kDa prion protein (PrP) with properties of both the normal and scraple-associated forms of PrP*, The Journal of Biological Chemistry, vol. 270, no. 7, issue of February 17, pp. 3299-3305, (1995).
X23	Product Description, "Proteinase K", Fermentas Life Sciences, http://www.fermentas.com/profiles/modifyingenzymes/pdf/protk0491.pdf, 3 pages, (2004).
X24	Sarath, G., et al., "Protease assay methods", Proteolytic enzymes, Practical Approach, (ed. By Beynon, R.J., and Bond, J.S., Oxford University Press, New York, Oxford, pp. 25-55, (1989).
X25	Prusiner, S.B., et al., "Further purification and characterization of scraple prions"., Blochemistry, vol. 21, no. 26, pp. 6942-6950, (1982).
X26	Prusiner, S.B., et al., 'Gel electrophoresis and glass permeation chromatography of the hamster scrapie agent after enzymatic digestion and detergent extraction', Biochemistry, vol. 19, no. 21, pp. 4892-4898, (1980).

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)	Filing Date: July 8, 2003	Group: 1651

X27	Prusiner, S.B., et al., "Electrophoretic properties of the scrapie agent in agarose gels", Proc. Natl. Acad. Sci. USA, Microbiology, vol. 77, no. 5, pp. 2984-2988, (1980)
X28	Prusiner, S.B., et al., "Partial purification and evidence for multiple molecular forms of the scrapie agent", Biochemistry, vol. 17, no. 23, pp. 4993-4999, (1978).
X29	Sharp, R.J., et al., "Isolation and growth of hyperthermophiles", Applied Microbial Physiology: A Practical Approach, Ch. 2, Eds. Stanbury and Rhodes, OUP, pp. 23-52, (1997).
X30	Raymond, G.J., et al., "Molecular assessment of the potential transmissibilities of BSE and scrapie to humans"., Nature, vol. 388, pp. 265-288, (1997).
X31	Rubenstein, R., et al., "Concentration and distribution of infectivity and PrP <sup>50</sup> following partial denaturation of a mouse adapted and a hamster-adapted scrapic strain", Archives of Virology, vol. 139, pp. 301-311, (1994),
X32	Safar, J., et el., "Moleculer mass, blochemical composition, and physicochemical behavior of the infectious form of the scrapie precursor protein monomer", Proc. Natl. Acad. Sci. USA, vol. 87, pp. 6373-6377, (1990).
X33	Siezen, R.J., et al., "Homology modeling and protein engineering strategy of subtileses, the family of subtilisin- like serine proteinases"., Protein Engineering, vol. 4, no. 7, pp. 719-737, (1991).
X34	Taylor, D.M., "Inactivation of prions by physical and chemical means"., Journal of Hospital Infection, vol. 43 (supplement), pp. S69-S76, (1999).
X35	Taylor, D.M., et al., "Deconfaminetion studies with the agents of bovine spong form encephalopathy end scraple", Archives of Virology, vol. 139, pp. 313-326, (1994).
X36	Wille, H., et al., "Separation of scraple prion infectivity from PrP amyloid polymers", J. Mol. Biol., vol. 259, pp. 608-621, (1996).
X37	Corrected Evidence in Support, All opposition proceedings filed in corresponding Australien Opposition, January 20, 2006.